EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	Civil Action No. 17-944-JFB-SRF
v.	)	
HOSPIRA, INC.,	)	REDACTED - PUBLIC VERSION
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this **27th** day of **April, 2018**, the court having considered the parties' letter submissions and arguments regarding plaintiffs' request for production of 50 expired samples of defendant Hospira, Inc.'s ("Hospira") proposed generic epinephrine product in the above-captioned matter (D.I. 52; D.I. 53), IT IS HEREBY ORDERED THAT the request for samples made by plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par") is denied without prejudice for the reasons set forth below.

1. **Background.** On July 13, 2017, Par filed a complaint for patent infringement under the Hatch-Waxman Act against Hospira. (D.I. 1) The action relates to Abbreviated New Drug Application ("ANDA") No. 208908, which was filed by Hospira with the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of Par's Adrenalin® epinephrine injection, 1 mg/mL ("the Hospira ANDA Product") prior to the expiration of the patents-in-suit. (D.I. 1 at ¶ 24) The Adrenalin® product is a clear, colorless, sterile parenteral solution containing the active ingredient L-epinephrine, which is intended for intramuscular or

subcutaneous administration, and is indicated for emergency treatment of allergic reactions, including anaphylaxis. (*Id.* at ¶ 13) Par is the holder of New Drug Application ("NDA") No. 204200 for Adrenalin® brand epinephrine injection 1 mg/mL. (*Id.* at ¶ 13) Par's Adrenalin® products are indicated for emergency treatment of allergic reactions, including anaphylaxis. (*Id.* at ¶ 13)

2. The complaint alleges infringement of U.S. Patent Nos. 9,119,876 ("the '876 patent") and 9,295,657 ("the '657 patent") (together, the "patents-in-suit"). (*Id.* at ¶ 1) The '876 patent, entitled "Epinephrine Formulations," was issued on September 1, 2015 to Par Pharmaceutical, Inc. as assignee. (*Id.* at ¶ 9) The '876 patent claims are directed to compositions comprising epinephrine, a tonicity regulating agent, a pH raising agent, an antioxidant comprising sodium bisulfite and/or sodium metabisulfite, a pH lowering agent, and a transition metal complexing agent, in certain ranges. (*Id.* at ¶ 21) The '657 patent, which is also entitled "Epinephrine Formulations," was issued on March 29, 2016 to Par Pharmaceutical, Inc. as assignee. (*Id.* at ¶ 11) Plaintiffs own and have exclusive rights to the patents-in-suit, including all rights to sue for infringement. (*Id.* at ¶¶ 9, 11) The '657 patent covers methods of using the inventive formulations to treat Type 1 allergic reactions, including anaphylaxis, by administering the composition claimed in the '876 patent. (*Id.* at ¶ 22)

3. On December 1, 2017, Par served its first set of requests for production of documents on Hospira.[1] Par's Request for Production No. 3 sought the production of "[f]ifty (50) representative samples of Hospira's Proposed Generic Product from each manufacturing

[1] The court does not consider Par's request for the samples untimely. However, in response to Hospira's argument on the untimeliness of the request, Par notes that it made a pre-suit request for Hospira's samples after receipt of Hospira's notice letter of its ANDA (D.I. 52 at 1-2), which included its Paragraph IV certification, *see* 21 U.S.C. § 355.

lot." (D.I. 52, Ex. A at 5-6) Hospira objected to the request on January 9, 2018, challenging the relevance and proportionality of the request in light of Hospira's production of its entire ANDA to Par. (*Id.* at 6)

4. On February 8, 2018, Par sent a letter to Hospira requesting samples of the ANDA product in response to Request for Production No. 3. (D.I. 52, Ex. B) Hospira responded to Par's letter request on February 15, 2018, declining to produce the samples of its ANDA products due to Par's failure to make a showing of relevance. (*Id.*, Ex. C) The parties met and conferred on March 16, 2018.

5. The court held a discovery dispute hearing on April 25, 2018. In its letter submission and during the hearing, Hospira explained that the requested samples were not relevant because they had expired, and were therefore not marketable upon approval of the ANDA. (D.I. 53 at 3) Specifically, the batches of Hospira's ANDA product that were submitted to the FDA were manufactured in [redacted] (*Id.*) Consequently, even the most recent batches are [redacted] and have exceeded their [redacted] shelf life. (*Id.*)

6. **Legal standard.** Pursuant to Rule 26,

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). A party may move for an order compelling discovery pursuant to Rule 37. Generally, a party moving to compel discovery bears the burden of demonstrating the relevance of the requested information. *See Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A.

Nos. 13-2108-RGA, 13-2109-RGA, 13-2122-RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016) (citing *Inventio AG v. ThyssenKrupp Elevator Am. Corp.*, 662 F. Supp. 2d 375, 381 (D. Del. 2009)). However, "[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment.

7. **Analysis.** Par's request to compel the production of samples of Hospira's proposed generic epinephrine product in response to Par's Request for Production No. 3 is denied without prejudice. Par has not adequately established that the requested discovery is relevant and proportional to the needs of the case where, as here, Hospira produced its entire ANDA. *See Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279-80 (Fed. Cir. 2013) ("[I]f an ANDA specification defines a compound such that it meets the limitations of an asserted claim, then there is almost never a genuine issue of material fact that the claim is infringed," and production of samples is unnecessary); *Bayer AG v. Elan Pharm. Res. Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000) (concluding that, where the ANDA directly addresses the question of infringement, the production of samples is unwarranted).

8. Par does not dispute that the ANDA specifies the concentration of each ingredient in Hospira's ANDA product, including the allowable percentage of variance in each commercial batch. (D.I. 52 at 2-3; D.I. 13, Ex. D) Instead, Par alleges that the expired samples of Hospira's ANDA product are relevant to claims 12 to 19 of the patents-in-suit, which are directed to a composition with levels of impurities arising after eighteen months of storage. (D.I. 52 at 2; 4/25/18 Tr.) In support of its position, Par relies primarily on the Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568-69 (Fed. Cir. 1997). However, the drug at issue in *Glaxo* involved a compound capable of existing in various forms. As a result, the

question of infringement was not straightforward, and the Federal Circuit concluded that the infringement inquiry should be based on evidence beyond the ANDA itself. *Id.* In *Sunovion* and *Bayer*, the Federal Circuit distinguished its prior decision in *Glaxo* based on the sufficiency of the ANDA itself, and reiterated the general rule that samples need not be produced if the ANDA adequately sets forth the composition of the generic product. *See Sunovion*, 731 F.3d at 1279-80; *Bayer*, 212 F.3d at 1249-50. Similar to the circumstances before the Federal Circuit in *Sunovion* and *Bayer*, there is no assertion in the present case that the ANDA itself is insufficient to establish the formulation of the ANDA product. For this reason, the court declines to compel the production of samples of Hospira's ANDA product.

9. The expiration of Hospira's ANDA samples further weighs against the relevance of the samples to the infringement inquiry. The law is well-established that the infringement inquiry in an ANDA case focuses on what will likely be marketed under the ANDA, and not the measurement of actual materials. *See Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1346, 1349 (Fed. Cir. 2002). Courts have held that evidence derived from an expired product is not relevant to the question of what will be sold for purposes of the infringement inquiry. *See SmithKline Beecham Corp. v. Apotex Corp.*, 2002 WL 1613724, at *2 (N.D. Ill. July 17, 2002).

10. Hospira has offered to produce additional documents in lieu of producing expired samples of its ANDA product. Consistent with Hospira's offer, on or before May 25, 2018, Hospira shall complete its production of "any and all relevant stability data and testing on its ANDA product presently in its possession, custody, and control." (D.I. 53 at 4) This production shall include "testing for 12 months of stability under the conditions specified by claims 12-19 of the patents-in-suit, as well as testing up to 24 months at different storage conditions." (*Id.*) Hospira shall also "produce any and all relevant documents related to the [redacted] of any

component in its formulation, and any test data reflecting [redacted] in its ANDA product," to the extent these documents have not already been produced. (*Id.* at 2) If Hospira's production gives rise to new or additional bases for Par to seek production of the expired samples of Hospira's ANDA product, Par may renew its request at that time.

11. Consistent with the court's statement on the record during the April 25, 2018 discovery dispute teleconference, Hospira is ordered to preserve the fifty expired samples of its ANDA product in its possession until further order of the court.

12. Conclusion. In view of the foregoing analysis, Par's request for production of samples of Hospira's ANDA product is denied without prejudice. Hospira shall produce the stability data discovery in accordance with paragraph 10 of this Memorandum Order on a rolling basis, to be fully completed on or before **May 25, 2018.** In addition, Hospira shall preserve the fifty expired samples of its ANDA product in its possession until further order of the court.

13. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties should jointly submit a proposed redacted version by no later than **May 7, 2018**. The court will subsequently issue a publicly available version of its Memorandum Order.

14. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to ten (10) pages each.

15. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge